DETAILED ACTION

Status of Claims

1. The amendment and remarks filed October 14, 2009 are acknowledged. Claims 1-10 are cancelled. Claims 11-17 have been added and are supported by the previous claims.

Specification

2. The abstract of the disclosure is objected to because the abstract uses the term “absorbs” to explain that the animal licks the preparation off its paw to effect oral administration. "Absorbs" is an inaccurate word to describe this method of oral administration. Correction is required. See MPEP § 608.01(b).

Priority

3. This application, filed July 10, 2006, is a national stage entry of PCT/EP2005/000067, filed January 7, 2005 and claims foreign priority to German Application 102004001558.9, filed January 10, 2004.

Withdrawn Rejections

4. The rejection of claims 1 and 10 under 35 U.S.C. 102(b) as being anticipated by Miller et al. (US 5,122,377) is withdrawn in view of Applicants’ amendments.

5. The rejection of claims 1-2 and 10 under 35 U.S.C. 103(a) as being unpatentable over an invention in public use in this country, more than one year prior to the date of application for Patent in the United States, in view of Miller et al. (US 5,122,377) is withdrawn in view of Applicants’ amendments.

6. The rejection of claims 3 and 5 under 35 U.S.C. 103(a) as being unpatentable over Watts et al. (US 6,191,143) in view of Miller et al. (US 5,122,377) is withdrawn in view of Applicants' amendments.

7. The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Endler et al. (WO 01/08682) in view of Miller et al. (US 5,122,377) is withdrawn in view of Applicants' amendments.

8. The rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Mertin et al. (US 2006/0177414) in view of Miller et al. (US 5,122,377) is withdrawn in view of Applicants' amendments.

9. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Hundley et al. (US 6,465,460) in view of Miller et al. (US 5,122,377) is withdrawn in view of Applicants' amendments.

10. The rejection of claims 7 and 9 under 35 U.S.C. 103(a) as being unpatentable over De Spiegeleer et al. (US 2006/0240049) in view of Miller et al. (US 5,122,377) is withdrawn in view of Applicants' amendments.

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,122,377) (pub. June 16, 1992) in view of an invention in public use in this country, more than one year prior to the date of application for Patent in the United States (Hairball Remedies) (2002) as evidenced by Hartz (Drugs.com veterinary edition).

Regarding claim 11, Miller et al. teach a composition for oral delivery of veterinary medication where the product can be administered orally by inducing the

animal to lick a dispensed quality from a surface, such as the animal's paw (Column 7, lines 31-35 and lines 47-48). Therefore, the animal is treated by applying the composition to its paw. The examiner submits that the animal's paw is covered by the coat of the animal, and thus the composition is applied to the animal's coat. The composition contains an active ingredient, such as amoxicillin, which is taken up orally by the animal (Column 7, lines 46-48 and column 8, lines 1-3). Miller et al. teach that the viscosity of the composition can be modified by heating and cooling and by adjusting the amount of capric/caprylic acid and capric/caprylic/stearic triglycerides (column 3, lines 17-27). Miller et al. also teach that the composition may be processed as a pourable liquid but becomes a semisolid medium for ease of administration, proper texture, and uniformity of the drug to be dosed (column 1, lines 19-30). It would have been within the purview of the skilled artisan to adjust the viscosity of the final product to be more fluid since Miller et al. teach several methods for modifying the viscosity. However, Miller et al. do not specifically teach that the formulation is applied to a cat. Hairball Remedies as evidenced by Hartz cure this deficiency.

Hairball remedies targeted to cats, dogs, rabbits, and other mammals have been in use in the United States since at least 2002 (*See* FDA September/October 2002 newsletter, available at http://www.fda.gov/cvm/Documents/SeptOct.pdf). One such example of a hairball remedy is Hartz Advanced Care Hairball Remedy (first used in commerce in 2003). This product is directed to cats and rabbits and the directions for use include applying the preparation to the pet's front paws where it can be licked off

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readily (*See* Drugs.com Veterinary Edition, available at http://www.drugs.com/vet/hartz-advanced-care-hairball-remedy.html).

It would have been prima facie obvious to combined the teachings of Miller et al. with those of Hairball Remedies as evidenced by Hartz to apply the composition of Miller et al. to the paw, and thus coat, of a cat. One would have been motivated to do so because Miller et al. teach the application of a pharmaceutical preparation to the paw of an animal, wherein the animal then orally takes up the formulation and Hairball remedies as evidenced by Hartz teach that this method of oral administration is used on cats.

15. Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,122,377) (pub. June 16, 1992) in view of an invention in public use in this country, more than one year prior to the date of application for Patent in the United States (Hairball Remedies) (2002) as evidenced by Hartz (Drugs.com veterinary edition) as applied to claim 11 above, and further in view of Endler et al. (WO 01/08682 A2) (pub. Feb. 8, 2001) (Derwent Abstract).

The combination of Miller et al. in view of Hairball Remedies and Hartz teach each limitation of claim 11 but fail to teach that flupirtine is substituted for amoxicillin. Endler et al. cure this deficiency.

Regarding claims 12 and 17, Endler et al. teach the use of flupirtine or its salt, administered orally, for the treatment of pain in cats and dogs (Equivalent-Abstracts).

It would have been prima facie obvious to combined the teachings of Miller et al. and Hairball Remedies as evidenced by Hartz with those of Endler et al. to substitute

flupirtine or its salt for amoxicillin to apply the composition of Miller et al. to the paw, and thus coat, of a cat. One would have been motivated to do so because Miller et al. teach the application of a pharmaceutical preparation to the paw of an animal, wherein the animal then orally takes up the formulation and Hairball remedies as evidenced by Hartz teach that this method of oral administration is used on cats. Endler et al. teach the oral administration of flupirtine or its salts via granules or tablets and Miller et al. teach that these dosage forms are difficult to administer and that the drugs may instead be administered via Miller et al.'s delivery system (Endler et al. Derwent abstract, Equivalant-Abstract and Miller et al., column 1, lines 10-18).

16. Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,122,377) (pub. June 16, 1992) in view of an invention in public use in this country, more than one year prior to the date of application for Patent in the United States (Hairball Remedies) (2002) as evidenced by Hartz (Drugs.com veterinary edition) as applied to claim 11 above, and further in view of Mertin et al. (DE 10224086) (pub. Nov. 12, 2003) (Machine Translation).

The combination of Miller et al. in view of Hairball Remedies and Hartz teach each limitation of claim 11 but fail to teach that enrofloxacin or pradofloxacin are substituted for amoxicillin. Mertin et al. cure this deficiency.

Regarding claims 13-14 and 17, Mertin et al. teach the oral administration of enrofloxacin or pradofloxacin to cats (p. 3-4).

It would have been prima facie obvious to combined the teachings of Miller et al. and Hairball Remedies as evidenced by Hartz with those of Mertin et al. to substitute enrofloxacin or pradofloxacin for amoxicillin to apply the composition of Miller et al. to the paw, and thus coat, of a cat. One would have been motivated to do so because Miller et al. teach the application of a pharmaceutical preparation to the paw of an animal, wherein the animal then orally takes up the formulation and Hairball remedies as evidenced by Hartz teach that this method of oral administration is used on cats. Mertin et al. teach the oral administration of enrofloxacin or pradofloxacin via an aqueous suspension which becomes thickened with a structure-viscous polymer (p. 2). Miller et al. teach that their invention may deliver a paste for oral administration and therefore, one of ordinary skill in the art would be motivated to use the thickened aqueous suspension of Mertin et al. in Miller et al.'s delivery system.

17. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,122,377) (pub. June 16, 1992) in view of an invention in public use in this country, more than one year prior to the date of application for Patent in the United States (Hairball Remedies) (2002) as evidenced by Hartz (Drugs.com veterinary edition) as applied to claim 11 above, and further in view of Kennedy (US 6,150,361) (pub. Nov. 21, 2000).

The combination of Miller et al. in view of Hairball Remedies and Hartz teach each limitation of claim 11 but fail to teach that toltrazuril or ponazuril are substituted for amoxicillin. Kennedy cures this deficiency.

Regarding claims 15-17, Kennedy teaches the oral administration of toltrazuril or ponazuril to cats (column 2, lines 22-67; column 4, lines 66-67; column 5, lines 23-29 and column 6, example 1 and table 1)).

It would have been prima facie obvious to combined the teachings of Miller et al. and Hairball Remedies as evidenced by Hartz with those of Kennedy to substitute toltrazuril or ponazuril for amoxicillin to apply the composition of Miller et al. to the paw, and thus coat, of a cat. One would have been motivated to do so because Miller et al. teach the application of a pharmaceutical preparation to the paw of an animal, wherein the animal then orally takes up the formulation and Hairball remedies as evidenced by Hartz teach that this method of oral administration is used on cats. Kennedy teaches the oral administration of toltrazuril or ponazuril via a suspension, tablet, capsule, gel or paste (column 5, lines 23-29). Miller et al. teach that their invention may deliver a paste for oral administration or that their system may be used to deliver drugs typically delivered in tablets or capsules, dosage forms that are difficult to administer (Miller et al., column 1, lines 10-18). Therefore, one of ordinary skill in the art would be motivated to use the orally administered drugs of Kennedy et al. in Miller et al.'s delivery system.

Response to Arguments

18. Applicants' arguments with regard to claims 1-2 and 10, which are similar in scope to new claims 11 and 17, are noted and have been fully considered but are not found persuasive. Applicants argue that the examiner has used impermissible hindsight to arrive at the instant invention. The examiner respectfully disagrees. Miller et al. teach

each aspect of claim 11 except that the preparation is specifically applied to a cat. Known hairball remedies, include applying a preparation to an animal's paw which the animal then takes up orally, thus teaching a method of oral administration of a preparation. Miller et al. teach an oral preparation to be administered to an animal by inducing the animal to lick a dispensed quality from a surface, such as an animal's paw. The known hairball remedy teaches that the same method is used on a cat. The examiner submits that applying the preparation a cat's paw necessarily means that the preparation is applied to the cat's coat, since the coat covers the paw.

19. The remainder of Applicant's arguments depend on the above argument and therefore are not further addressed.

Conclusion

No claims are allowed.

New grounds of rejection were necessitated in this Office Action only because of Applicants' amendments. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 36 CRF 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./
Examiner, Art Unit 1611

/David J Blanchard/
Primary Examiner, Art Unit 1643